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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,786	08/27/2003	Jian Ni	1488.130000B/EKS/EJH	5264

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EXAMINER	
KAUFMAN, CLAIRE M	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
07/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,786	NI ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-30 and 33-77* is/are pending in the application.

4a) Of the above claim(s) *45-48,50,69-72 and 74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-30,33-44,49,51-68,73 and 75-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *26-30 and 33-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

The rejection of claim 26 and dependent claims under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claim.

The rejection of claims under 35 USC 112, first paragraph, is withdrawn in view of the Statement Concerning the Deposited cDNA Clone filed 6/11/07.

Information Disclosure Statement

The first supplemental IDS filed 4/12/04 is being resent to indicate that references AB2 and AC2 have been considered. There references do not affect that patentability of the claimed invention.

Double Patenting

Claims 26-30, 33-36, 40, 42- 44, 51-62, 66, 68 and 75-77 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 14, 26, 28, 40, 42, 54, 56, 66, 68, 78, 80, 90, 92, 102, 104, 116, 118, 130, 132, 144, 146, 158, 160, 170, 172, 182, 184, 194, 196, 209, 211, 212, 214, 215, 217, 218 and 220 of U.S. Patent No. 7,060,272 as set forth in the previously Office action: Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims are drawn to either a method of inducing apoptosis or treating cancer by administering both an antibody that binds DR4 or the extracellular domain thereof and a chemotherapeutic agent, or to a composition comprising the antibody and a chemotherapeutic agent. Note that patent claim 139, for example, designate the antibody as being a chimeric, Fab fragment or F(ab') fragment, and claims137 and 138 designate the antibody as being monoclonal or polyclonal. Claim 9, for example, designates that antibody is labeled with an enzyme, which is a heterologous polypeptide.

Claims 37-41 and 63-67 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 14, 26, 28, 40, 42, 54, 56, 66, 68, 78, 80, 90, 92, 102, 104, 116, 118, 130, 132, 144, 146, 158, 160, 170, 172, 182, 184, 194, 196, 209, 211,

212, 214, 215, 217, 218 and 220 of U.S. Patent No. 7,060,272 as applied above and in view of U.S. 6,025,158 as set forth in the previously Office action:

US 7,060,272 does not claim single chain, humanized, human or pegylated antibodies.

U.S. 6,025,158 teaches antibodies for treatment which are single chain (*e.g.*, col. 12, lines 26-40), humanized (*e.g.*, col. 59, lines 50-67), human (*e.g.*, col. 38, lines 55-64) and pegylated (*e.g.*, col. 43, lines 21-62), which were well known in the art at the time the invention was made.

Because these types of antibodies were well known at the time the invention was made and their advantages were recognized as shown in US 6,025,158, having the methods and compositions of US 7,060,272 comprise antibodies with these characteristics would have been obvious at the time the invention was made.

Claims 49 and 73 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 14, 26, 28, 40, 42, 54, 56, 66, 68, 78, 80, 90, 92, 102, 104, 116, 118, 130, 132, 144, 146, 158, 160, 170, 172, 182, 184, 194, 196, 209, 211, 212, 214, 215, 217, 218 and 220 of U.S. Patent No. 7,060,272 as applied above and in view of Base et al. (Int. Urology and Nephrology 16(2):157-164, 1984) as set forth in the previously Office action:

US 7,060,272 does not claim a platinum analogue as a chemotherapeutic.

Base et al. teach the advantage of using cis-platin as a chemotherapeutic for the treatment of certain testicular tumors, reporting that "The adoption of cis-platin in the treatment of malignant testicular tumours by Einhorn and Donohue meant a major contribution."

It would have been obvious at the time the invention was made to use a platinum analog such as cis-platinum as a chemotherapeutic because such analogues were old in the art and recognized as having important chemotherapeutic properties as exemplified in Base et al.

Claims 26-30, 33-44, 49, 51-68, 73, 75-77 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-146 of U.S. Patent No.

6,461,823 in view of Base et al. (Int. Urology and Nephrology 16(2):157-164, 1984), U.S. Patent Nos. 6,025,158 and 5,763,223 as set forth in the previously Office action:

U.S. Patent No. 6,461,823 claims antibodies which bind DR4 [SEQ ID NO: 2 (or encoded by the cDNA contained in ATCC# 97853)] or a portion thereof, including the extracellular domain. Note that patent claim 4, for example, designates the antibody as being a chimeric, Fab fragment or F(ab') fragment, and claims 59 and 60 designate the antibody as being monoclonal or polyclonal. Claim 6, for example, designates that the antibody is labeled with an enzyme, which is a heterologous polypeptide. US 6,461,823, does not claim treatment of cancer, pegylation of the antibody, a human or humanized antibody or combining the antibody with a platinum analog.

US 5,763, 223 teaches using TRAIL to induce apoptosis in cancer cells for treating cancer (*e.g.,* col. 1, lines 60-63).

U.S. 6,025,158 teaches antibodies for treatment which are single chain (*e.g.*, col. 12, lines 26-40), humanized (*e.g.*, col. 59, lines 50-67), human (*e.g.*, col. 38, lines 55-64) and pegylated (*e.g.*, col. 43, lines 21-62), which were well known in the art at the time the invention was made.

Base et al. teach the advantage of using cis-platin as a chemotherapeutic for the treatment of certain testicular tumors, reporting that "The adoption of cis-platin in the treatment of malignant testicular tumours by Einhorn and Donohue meant a major contribution."

It would have been obvious at the time the invention was made to use an anti-DR4 antibody to treat cancer because DR4 bound TRAIL , which binding induced apoptotisis (see Fig. 6A and col. 6, lines 44-48, of US 6,461,823) and TRAIL was disclosed by US 5,763,223 as having the ability to induce apoptosis in cancers. Therefore, an antibody that bound and activated DR4 would have reasonably been expected to have TRAIL-like apoptosis inducing activity. It further would have been obvious to use a platinum analog such as cis-platinum as a chemotherapeutic with an anti-DR4 antibody because such analogues were old in the art and recognized as having important chemotherapeutic properties as exemplified in Base et al. Further, because single chain, human, humanized and pegylated of antibodies were well known at the time the invention was made and their advantages were recognized as shown in US 6,025,158, having the methods and compositions of US 6,461,823 comprise antibodies with these characteristics would have been obvious at the time the invention was made.

Claims 26-30, 33-44, 49, 51-68, 73, 75-77 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-146 of U.S. Patent No. 6,943,020 in view of Base et al. (Int. Urology and Nephrology 16(2):157-164, 1984), U.S. Patent Nos. 6,025,158 and 5,763,223 as set forth in the previously Office action:

U.S. Patent No. 6,943,020 claims antibodies which bind DR4 [SEQ ID NO: 2 (or encoded by the cDNA contained in ATCC# 97853)] or a portion thereof, including the extracellular domain. Note that patent claim 5, for example, designates the antibody as being a chimeric, Fab fragment or F(ab') fragment, and claims 4 and 3 designate the antibody as being monoclonal or polyclonal. Claim 7, for example, designates that the antibody is labeled with an enzyme, which is a heterologous polypeptide. US 6,943,020, does not claim treatment of cancer, pegylation of the antibody, a human or humanized antibody or combining the antibody with a platinum analog.

US 5,763, 223 teaches using TRAIL to induce apoptosis in cancer cells for treating cancer (col. 1, lines 60-63).

U.S. 6,025,158 teaches antibodies for treatment which are single chain (*e.g.*, col. 12, lines 26-40), humanized (*e.g.*, col. 59, lines 50-67), human (*e.g.*, col. 38, lines 55-64) and pegylated (*e.g.*, col. 43, lines 21-62), which were well known in the art at the time the invention was made.

Base et al. teach the advantage of using cis-platin as a chemotherapeutic for the treatment of certain testicular tumors, reporting that "The adoption of cis-platin in the treatment of malignant testicular tumours by Einhorn and Donohue meant a major contribution."

It would have been obvious at the time the invention was made to use an anti-DR4 antibody to treat cancer because DR4 bound TRAIL , which binding induced apoptotisis (see Fig. 6A and col. 6, lines 44-48, of US 6,943,020) and TRAIL was disclosed by US 5,763,223 as having the ability to induce apoptosis in cancers. Therefore, an antibody that bound and activated DR4 would have reasonably been expected to have TRAIL-like apoptosis inducing activity. It further would have been obvious to use a platinum analog such as cis-platinum as a chemotherapeutic with an anti-DR4 antibody because such analogues were old in the art and recognized as having important chemotherapeutic properties as exemplified in Base et al. Further, because single chain, human, humanized and pegylated of antibodies were well known

at the time the invention was made and their advantages were recognized as shown in US 6,025,158, having the methods and compositions of US 6,943,020 comprise antibodies with these characteristics would have been obvious at the time the invention was made.

Applicants' traversal of the above rejections in the response filed 6/11/07 is acknowledged. Applicants did not distinctly and specifically point out the reason(s) for traversal. Applicants' request that the rejections be held in abeyance until subject matter that might otherwise be patentable is identified is acknowledged. It would be appropriate in response to this Office action to file terminal disclaimers and/or supply complete traversals of the rejections.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire M. Kaufman, Ph.D.
Patent Examiner, Art Unit 1646
July 24, 2007

LORRAINE SPECTOR
PRIMARY EXAMINER